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(54) Title: FERMENTATION PROCESS FOR THE PREPARATION OF PRAVASTATIN

(57) Abstract: The invention relates to a fermentation process for the preparation of substantially pure pravastatin. The process provides a method of producing pravastatin by microbial hydroxylation of compactin (ML-236B) by maintaining a concentration of compactin at not less than 300 µg /ml during the process. The process produces substantially pure pravastatin with reduced related impurities. The invention also relates to pharmaceutical compositions that include the substantially pure pravastatin.

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